LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES
1600 STEWART AVENUE
WESTBURY, NY 11590
(516) 222-6222
FAX (516) 683-1887

February 10, 2000

00 FEB 11 AM 10:51 40119

OVERNIGHT DOCUMENT

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Prozac (Fluoxetine) Tablets, 20 mg, (NDA-20-974), by Eli Lilly and Company, have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA-approved drug products. The Orange Book currently lists Prozac (Fluoxetine) Tablets, 20 mg in the Prescription Drug Product List section. A listing in this section of the Orange Book indicates that the specific drug product is the subject of an approved application. However, based on a survey of the marketplace, Prozac Tablets, 20 mg, are not available for sale to the consumer.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drugs application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or

00P-0585

CP 1

LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

effectiveness before an ANDA that refers to that list drug may be approved [21 CFR 314.161(a)(1)].

As stated, Eli Lilly and Company's Prozac Tablets, 20 mg, are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product, it is requested that the FDA determine whether Eli Lilly's decision not to market Prozac Tablets, 20 mg, was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided if so requested.

E. Certification

The undersigned certifies that, to its best knowledge and belief, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock

Robert W. Pollock
Vice President

RP/db

Enclosure: *Cumulative Supplement No. 9, p. 22*

cc: L. Lachman
G. Johnston

Gcp0041

ETRETINATE

CAPSULE; ORAL

T	TEGISON			
T	ROCHE	10MG		N19369 001 SEP 30, 1986
T	*	25MG		N19369 002 SEP 30, 1986
D	@	10MG		N19369 001 SEP 30, 1986
D	@	25MG		N19369 002 SEP 30, 1986

FERRIC SODIUM GLUCONATE

INJECTABLE; INJECTION

	FERRLECIT		
+	R AND D LABS	62.5MG/5ML	N20955 001 FEB 18, 1999

FLUOCINONIDE

OINTMENT; TOPICAL

	FLUOCINONIDE		
AB	TARO	0.05%	N75008 001 JUN 30, 1999

FLUOROURACIL

INJECTABLE; INJECTION

	FLUOROURACIL		
AP	BIGMAR	50MG/ML	N40291 001 MAR 24, 1999
AP	SMITH AND NEPHEW	50MG/ML	N88767 001 DEC 28, 1984
AP		50MG/ML	N89434 001 MAR 26, 1987
@		50MG/ML	N88767 001 DEC 28, 1984
@		50MG/ML	N89434 001 MAR 26, 1987

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

	PROZAC		
*	LILLY	EQ 20MG BASE	N18936 001 DEC 29, 1987
		EQ 20MG BASE	N18936 001 DEC 29, 1987
+		EQ 40MG BASE	N18936 003 JUN 15, 1999
@		EQ 60MG BASE	N18936 004 JUN 15, 1999

TABLET; ORAL

	PROZAC		
	LILLY	EQ 10MG BASE	N20974 001 MAR 09, 1999
*		EQ 20MG BASE	N20974 002 MAR 09, 1999
+		EQ 10MG BASE	N20974 001 MAR 09, 1999
@		EQ 20MG BASE	N20974 002 MAR 09, 1999

FOLIC ACID

TABLET; ORAL

	FOLIC ACID		
> DLT >			
> ADD >			
AA	VINTAGE PHARMS	1MG	N86296 001
@		1MG	N86296 001

FUROSEMIDE

INJECTABLE; INJECTION

	FUROSEMIDE		
AP	ABBOTT	10MG/ML	N75241 001 MAY 28, 1999
AP	SMITH AND NEPHEW	10MG/ML	N70078 001 FEB 05, 1986
@		10MG/ML	N70078 001 FEB 05, 1986
AP	STERIS	10MG/ML	N70019 001 SEP 22, 1986
AP		10MG/ML	N70604 001 JAN 02, 1987
@		10MG/ML	N70019 001 SEP 22, 1986

Please place special services sticker here if necessary

Attach the Airborne Express Shippers Label within the dotted lines.

PLEASE TYPE OR PRINT

FOR SHIPMENTS WITHIN U.S. ONLY

001 (3/96)M-06 PACKAGE LABEL

FROM

LACHMAN CONSULTANT SVC

160U STEWART AVE .

WESTBURY NY 11590

516-683-1001

TO

Docket Management Branch
HFA-305
5600 Fishers Lane (HFA-305)
Rockville MD

7426559980

Preprint Format No. 495 21663

Origin LIA Airbill Number 7426559980

Method of Payment (Assumed sender unless otherwise noted)

- [X] Bill Sender
- [ ] Bill Receiver
- [ ] Bill 3rd Party
- [ ] Paid in Advance

AIRBORNE EXPRESS.

EXP (Letter - 150 lbs) X

NAS (Letter - 5 lbs)

SDS (Letter - 150 lbs)

Billing Reference will appear on invoice

No. of Pkgs	Weight(LBS)	One box must be checked: Letter Express	Express Pack	Other Packaging
1				

Special Instructions

- [ ] SAT
- [ ] HAA
- [ ] LAB

PEEL BACK FROM

742 655 998

MLDA ABH 4X

United States Shipping

1. Complete applicable white sections of the U.S. Airbill. Sign and date the Airbill at the Sender's Signature line. Please press hard.
2. Peel off protective covering from back of Airbill.
3. Affix Airbill to envelope within dotted lines shown.
4. When using a Drop Box – follow special instructions on the Drop Box.

International Shipping

Includes Canada & Puerto Rico

Must be typed

1. Complete applicable white sections of the International Express Airbill. Sign and date the Airbill at the Sender's Signature line.

Limitation on Contents

The maximum acceptable contents of a Letter Express is forty 8-1/2 x 11 pages. If the gross weight of the contents, envelope a airbill exceeds 1/2 pound, the next higher rate will apply. Cont must be of a size and shape which fit the envelope and allow it securely sealed without damage. Cash or cash equivalent shou be shipped. Items of high intrinsic value should not be shipped Letter Express packaging.

Limitations of Liability

Liability of Airborne Express is limited on Letter Express to $1 U.S.D., unless a higher value is declared for carriage on our ai The maximum declared value on the Letter Express is $500.00